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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

JONNIE HOMYK, individually and on behalf of all others similarly situated, Plaintiff, v. CHEMOCENTRYX, Inc. and THOMAS J. SCHALL, Defendants.	Case No. _____ **Class Action Complaint for Violations of the Federal Securities Laws** **Jury Trial Demanded**

Plaintiff, Jonnie Homyk, ("Plaintiff"), by and through her attorneys, alleges upon personal knowledge as to her own acts, and upon information and belief as to all other matters, based upon the investigation conducted by and through her attorneys, which included, among other things, a review of documents filed by Defendants (as defined below) with the United States Securities and Exchange Commission (the "SEC"), news reports, press releases issued by Defendants, and other publicly available documents, as follows:

Nature and Summary of the Action

1. This is a federal securities class action on behalf of all investors who purchased or otherwise acquired ChemoCentryx, Inc. ("ChemoCentryx" or the "Company") common stock between November 26, 2019 and May 3, 2021, inclusive (the "Class Period"), seeking to recover damages caused by Defendants' violations of the federal securities laws and to pursue remedies under §§ 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5.

2. ChemoCentryx is a biopharmaceutical company focused on the development and commercialization of new medications targeting inflammatory disorders, autoimmune diseases, and cancer. The Company commenced operations in 1997. ChemoCentryx's lead drug candidate is avacopan, which the Company describes as "a potential first-in-class, orally-administered molecule that employs a novel for the treatment of patients with ANCA vasculitis. ChemoCentryx common stock trades on the NASDAQ stock exchange under the ticker symbol "CCXI." The Company is headquartered in San Carlos, CA.

3. After the market closed on November 25, 2019, ChemoCentryx announced "Positive Topline Data from Pivotal Phase III ADVOCATE Trial Demonstrating Avacopan's Superiority Over Standard of Care in ANCA-Associated Vasculitis." In this announcement, ChemoCentryx stated that the ADVOCATE Phase III Trial "met both of its primary endpoints," and that "[t]he topline safety results revealed an acceptable safety profile in this serious and life-threatening disease."

4. Moreover, Defendant Thomas J. Schall, the Company's President, CEO, and Chairman of the Board of Directors, stated that "[t]hese results exceed our expectations. Today we mark the dawn of a new and historic period in the lives of ANCA vasculitis patients. This day we have for the first time demonstrated that a highly targeted therapy aimed at the very center of the ANCA disease process is superior to the traditional approach of broad immune suppression therapy; a therapy which the present findings may make obsolete. Until now ANCA vasculitis patients have had to endure regimens that contain chronic high doses of steroids and all their

noxious effects, but with today's data it is clear that the time of making patients sick with steroid therapy in an attempt to make their acute vasculitis better may at last be over."

5. On this news, ChemoCentryx shares soared from their November 25, 2019 close of $8.06 per share to a November 26, 2019 opening price of $34.82 – more than quadrupling the share price.

6. Over the next several months, as alleged herein, Defendants continued to repeatedly laud the results of the ADVOCATE Phase III trial, as well as the safety profile of avacopan for the treatment of ANCA-associated vasculitis. On July 9, 2020, ChemoCentryx announced that it had filed its New Drug Application ("NDA") for avacopan, and on September 17, 2020, the Company announced that the FDA had accepted the NDA for review. During the Class Period, ChemoCentryx shares traded to over $70.00 each.

7. On May 4, 2021, the United States Food and Drug Administration (the "FDA") published a Briefing Document concerning ChemoCentryx's NDA #214487 for avacopan. In this Briefing Document, the FDA wrote that "***[c]omplexities of the study design, as detailed in the briefing document, raise questions about the interpretability of the data to define a clinically meaningful benefit of avacopan and its role in the management of AAV***." (Emphasis added). The FDA Briefing Document continued that "[a]lthough primary efficacy comparisons were statistically significant, ***the review team has identified several areas of concern, raising uncertainties about the interpretability of these data and the clinical meaningfulness of these results*** . . . ." (Emphasis added). In the Briefing Document, the FDA also raised serious safety concerns with avacopan for the treatment of ANCA-associated vasculitis.

8. On this news, the price of ChemoCentryx common stock plummeted over 45% in one day, down from its May 3, 2021 closing price of $48.82 to a May 4, 2021 close of $26.63 per share, on unusually high trading volume. Shares traded intraday as low as $17.79 each. This represents a one-day loss of approximately $1.5 billion in market capitalization.

9. Throughout the Class Period and in violation of the Exchange Act, Defendants made materially false and/or misleading statements, as well as failed to disclose material adverse facts to investors. Specifically, Defendants misrepresented and/or failed to disclose to investors

that: (1) the study design of the Phase III ADVOCATE trial presented issues about the interpretability of the trial data to define a clinically meaningful benefit of avacopan and its role in the management of ANCA-associated vasculitis; (2) the data from the Phase III ADVOCATE trial raised serious safety concerns for avacopan; (3) these issues presented a substantial concern regarding the viability of ChemoCentryx's NDA for avacopan for the treatment of ANCA-associated vasculitis; and (4) as a result of the foregoing, Defendants' public statements were materially false and misleading at all relevant times.

10. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

Jurisdiction and Venue

11. The federal law claims asserted herein arise under and pursuant to §§ 10(b) and 20(a) of the Exchange Act, 15 U.S.C. § 78(b) and 78t(a), and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5.

12. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §1331, § 27 of the Exchange Act, 15 U.S.C. § 78aa.

13. This Court has jurisdiction over each Defendant named herein because each Defendant is an individual or corporation who has sufficient minimum contacts with this District as to render the exercise of jurisdiction by the District Court permissible under traditional notions of fair play and substantial justice.

14. Venue is proper in this District pursuant to § 27 of the Exchange Act, 15 U.S.C. § 78aa and 28 U.S.C. § 1931(b), as the Company has its principal executive offices located in this District and conducts substantial business here.

15. In connection with the acts, omissions, conduct and other wrongs in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to the United States mail, interstate telephone communications and the facilities of the national securities exchange.

Intradistrict Assignment

16. Pursuant to Local Rule 3-2(c), this is a securities fraud class action to be assigned on a district-wide basis. Defendant ChemoCentryx, Inc. is headquartered in San Carlos, CA, which is within the San Francisco/Oakland Division.

Parties

17. Plaintiff Jonnie Homyk, as set forth in her Certification filed contemporaneously herewith, acquired shares of ChemoCentryx common stock at artificially inflated prices, and has been damaged.

18. Defendant ChemoCentryx, Inc. is incorporated under the laws of the State of Delaware, with its principal place of business at 835 Industrial Road, San Carlos, CA 94070. Its common stock trades on the NASDAQ stock exchange under the symbol CCXI.

19. Defendant Thomas J. Schall, Ph.D., is ChemoCentryx's President, Chief Executive Officer, and Chairman of the Board of Directors. Defendant Schall has served as President and CEO since 1997, when he founded the Company, and was appointed Chairman of the Board in April 2012.

20. Defendant Schall is named as a Defendant for violations of all counts asserted herein, and is sometimes referred to as the "Individual Defendant." The Individual Defendant, because of his positions with the Company, possessed the power and authority to control the contents of the Company's reports to the SEC, press releases and presentations to securities analysts, money and portfolio managers, and the investing public, *i.e.*, the market. The Individual Defendant was provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of his positions and access to material, non-public information available to him, the Individual Defendant knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations that were being made were then materially false and/or misleading. The Individual Defendant is therefore liable for the misstatements and omissions plead herein.

Substantive Allegations

21. According to its most recent Annual Report filed on Form 10-K with the SEC on March 1, 2021, ChemoCentryx is a biopharmaceutical company focused on the development and commercialization of new medications targeting inflammatory disorders, autoimmune diseases, and cancer. The Company commenced operations in 1997. ChemoCentryx's lead drug candidate is avacopan for the treatment of patients with ANCA vasculitis.

Defendants' False and Misleading Statements and Omissions

22. The Class Period begins on November 26, 2019. After the market closed on November 25, 2019, ChemoCentryx issued a press release announcing "Positive Topline Data from Pivotal Phase III ADVOCATE Trial Demonstrating Avacopan's Superiority Over Standard of Care in ANCA-Associated Vasculitis."[1] This release provided, in relevant part, that:

> This global study, in which a total of 331 patients with acute ANCA vasculitis were enrolled, met both of its primary endpoints, disease remission at 26 weeks and sustained remission at 52 weeks, as assessed by the Birmingham Vasculitis Activity Score, or BVAS. Remission was defined as a BVAS score of zero and being off glucocorticoid treatment for ANCA vasculitis for at least the preceding four weeks. The pre-specified primary endpoints were remission of acute vasculitis activity at week 26 and sustained remission at week 52, where avacopan therapy was at least statistically non-inferior to the currently used glucocorticoid-containing standard of care (glucocorticoid SOC). The two primary endpoints were tested sequentially using a gatekeeping procedure to preserve the Type I error.
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> * * *
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> The topline safety results revealed an acceptable safety profile in this serious and life-threatening disease, with fewer subjects having serious adverse events (SAEs) in the avacopan group than in the glucocorticoid SOC control group (42% vs. 45%, respectively). Most reported SAEs were related to underlying ANCA vasculitis disease and commensurate with rates in previously published ANCA vasculitis trials. There were fewer subjects with serious infections in the avacopan group than the glucocorticoid SOC control group. A full analysis of the data is underway and expanded results are expected to be announced in the coming weeks.

23. In this November 25, 2019 announcement, Defendant Schall stated:

> These results exceed our expectations. Today we mark the dawn of a new and historic period in the lives of ANCA vasculitis patients. This day we have for the first time demonstrated that a highly targeted therapy aimed at the very center of the ANCA disease process is superior to the traditional approach of broad immune suppression therapy; a therapy which the present findings may make obsolete. Until

[1] https://www.sec.gov/Archives/edgar/data/0001340652/000119312519299865/d839895dex991.htm.

> now ANCA vasculitis patients have had to endure regimens that contain chronic high doses of steroids and all their noxious effects, but with today's data it is clear that the time of making patients sick with steroid therapy in an attempt to make their acute vasculitis better may at last be over. Working with our partner VFMCRP, we plan to make regulatory submissions for full marketing approval to both the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) in 2020.

24. In its November 25, 2019 release, ChemoCentryx announced that the data showed "[s]ignificant reduction in glucocorticoid-related toxicity," "significant improvement in kidney function in patients with renal disease," and "improvement in health-related quality of life metrics."

25. Also on November 25, 2019, ChemoCentryx held a call with analysts to discuss the results of its ADVOCATE Phase III trial. On this call, Defendant Schall stated "I'll mention as well, safety seems to be very acceptable. The drug was generally very well tolerated with lower incidences of [adverse events] in the ANCA patient population."

26. On February 19, 2020, ChemoCentryx issued a press release announcing that Defendant Schall would present at the 9th Annual SVB Leerink Healthcare Conference on February 26, 2020. In this press release, ChemoCentryx stated: "Avacopan is an orally-administered small molecule that is a selective inhibitor of the complement C5a receptor, or C5aR. In the pivotal Phase III ADVOCATE trial, avacopan demonstrated the ability to induce vasculitis remission at 26 weeks and statistical superiority in sustaining vasculitis remission at 52 weeks. The topline safety results revealed an acceptable safety profile in this serious and life-threatening disease with fewer subjects having serious after events in the avacopan group than in the glucocorticoid-containing standard of care."

27. The Company issued a press release dated March 3, 2020 containing similar language as that quoted *supra* in ¶ 26 from ChemoCentryx's February 19, 2020 press release.

28. On March 10, 2020, ChemoCentryx reported its Fourth Quarter and Full Year 2019 Financial Results. In the press release accompanying this announcement,[2] Defendant Schall stated:

> The power of data to transform the world was evident in the results of our Phase III ADVOCATE trial of avacopan in ANCA-associated vasculitis . . . . The

[2] https://ir.chemocentryx.com/news-releases/news-release-details/chemocentryx-reports-fourth-quarter-and-full-year-2019-financial.

> ADVOCATE data marked a critical turning point, in my view, in the treatment of this debilitating disease, with avacopan demonstrating superiority over the current standard of care which employs daily dosing of glucocorticoids. Those results transformed not just thousands of lives potentially, but changed the face of our enterprise as well. We intend to file an NDA for avacopan with the FDA by the middle of this year, and are laying the groundwork for US commercialization. Furthermore, the success of ADVOCATE not only validated the biology of C5a receptor inhibition by avacopan as a powerful therapy but it surpassed expectations and may open doors to additional renal disease opportunities in underserved indications such as lupus nephritis. The momentous readout in ADVOCATE now sets the stage for a data-rich 2020, during which we expect to share topline results from four additional ongoing clinical trials. An epochal year for CCXI was 2019, and we expect 2020 to be extraordinary as well.

29. ChemoCentryx's March 10, 2020 release further provided:

> Exceeded expectations for avacopan with topline data from the ADVOCATE Phase III pivotal clinical trial announced in the fourth quarter of 2019, which demonstrated avacopan's statistical superiority in sustaining remission at 52 weeks over the prednisone-containing standard-of-care, eliminating the need for daily noxious steroids. Avacopan was shown to lower all four aspects of the total burden of disease: stopping active vasculitis; significantly lowering current therapy-induced illness, with a statistically significant reduction in the Glucocorticoid Toxicity Index (GTI) and other accepted assessments of glucocorticoid toxicity; significantly improving kidney function as evidenced by a marked improvement in Estimated Glomerular Filtration Rate, or eGFR; and statistically significant improvements in quality of life, assessed by the SF-36 QOL instrument and the EuroQOL-5D-5L instrument (Visual Analogue Scale and EQ Index).

30. Also on March 10, 2020, the Company held a call with analysts to discuss its financial results. On this call, Defendant Schall stated:

> The result of the ADVOCATE trial surpassed all of our expectations and could mark a critical turning point in the treatment of this devastating, debilitating and life-threatening disease. The avacopan value proposition that we tested in the ADVOCATE trial was fourfold, as shown on Slide 5.
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> One, to stop the acute active vasculitis crisis in ANCA patients by stifling the activation of disease-causing neutrophils. These neutrophils are thought to be driven by the C5a receptor, which is the molecular target of avacopan. Two, by using avacopan instead of chronic daily steroids to eliminate illnesses caused by the current standard daily steroid therapy. Three, to stop the accumulation of organ damage, particularly and notably in the kidney. And four, to improve the all too often miserable quality of life of ANCA patients.
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> So let me briefly summarize the top line results, which you can find on Slide 6. First, you'll see that avacopan was numerically superior and statistically non-inferior to the daily steroid-containing active comparator at 26 weeks in achieving remission that is in stopping active vasculitis as measured by the Birmingham Vasculitis Activity Score, or BVAS, which was the tool used for the primary efficacy endpoints used in this trial.

> After 52 weeks of treatment, the avacopan therapy sustained remission at a rate of 65.7% compared to 54.9% in the active comparator arm. Not only was this numerically and statistically non-inferior to the incumbent standard of care, but this result was highly statistically significant for the superiority of avacopan in terms of sustained remission after 1 year.
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> Next, avacopan has achieved statistical superiority in reducing the illnesses that are associated with the use of steroids in the active comparator treatment, as compared -- or as measured, rather, by the Glucocorticoid Toxicity Index, a comprehensive quantitative scoring system developed by expert clinicians over the course of some years.
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> Third, avacopan showed a statistically significant improvement over the active comparator in Estimated Glomerular Filtration Rate, or eGFR. While our goal was originally to stabilize kidney function to save the kidney, it looks as though with avacopan, kidney function actually improves. This perhaps is the single data point that nephrologists are most interested in, and it has been a key factor as we contemplate future opportunities for avacopan, of which I will speak momentarily.
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> Finally, you can see that avacopan therapy was numerically superior to the active comparator standard of care in all 10 of 10 of the measurements and at each of the time points measured, while showing a statistically significant improvement in 6 of the 10 measurement categories assessed by the SF-36 validated quality of life instrument. Moreover, avacopan was also statistically significantly better in the European index, EuroQOL-5D-5L.
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> Avacopan thus demonstrated the ability to actually improve the quality of life over 1 year of treatment compared to a deterioration for those in the daily steroid-containing active comparator arm, a remarkable change in how patients perceive and report their health with an instrument validated by regulatory authorities. Avacopan superiority here includes physical and emotional functioning, including a significant improvement in the crucial category of vitality, which is so important in allowing patients to return to normal lives, with obvious socioeconomic benefits.
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> The top line safety results revealed an acceptable safety profile in the serious and life-threatening disease, with fewer subjects having serious adverse events in the avacopan group than in the daily steroid-containing active comparator. Putting this all together, we believe avacopan has a very strong value proposition as it demonstrated progress in all 4 key elements of the total burden of a disease, which leads thousands of lengthy -- two thousands of lengthy hospitalizations each and every year.

31. The Company issued a press release dated May 4, 2020 containing similar language as that quoted *supra* in ¶ 26 from ChemoCentryx's February 19, 2020 press release.

32. On May 11, 2020, the Company held an earnings call to discuss its First Quarter 2020 financial results. On this call, Defendant Schall stated:

> Our dialogue with the FDA continues on track, and we are on schedule to file our NDA for avacopan mid this year. Our confidence that we will meet this target was high to start with and has grown with each week that passes. It is a confidence that is founded upon what we consider to be the superlative results achieved in the

> pivotal Phase III ADVOCATE clinical trial in which avacopan demonstrated statistical superiority in sustained disease remission during 1 year of treatment versus the current steroid-containing standard of care group. This exceeded most expectations since the trial was not powered for superiority. Overall, the ADVOCATE trial revealed a compelling value proposition for avacopan and ANCA in the form of an all-around ability to reduce the total burden of ANCA-related disease.
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> Notably, beyond bringing the disease symptoms into remission and sustaining people in remission, as mentioned above, in addition, avacopan therapy significantly reduced the illnesses associated with the use of steroids, significantly improved kidney function over 52 weeks and actually improved quality of life, in contrast to the deterioration in quality of life in those patients on the steroid-containing standard of care. Members of the ANCA patient and clinician communities relate that touch effects are unprecedented in the ANCA vasculitis field, bringing the hope for a new paradigm of therapy.

33. On June 10, 2020, ChemoCentryx announced plans to commence an underwritten public offering of its common stock. On the same day, the Company filed a Prospectus on Form 424B5 with the SEC. This Prospectus provided, in relevant part:

> In November 2019, we announced positive topline data from the pivotal Phase III ADVOCATE trial of avacopan, our lead drug candidate that is an orally-administered selective complement 5a receptor inhibitor, for the treatment of patients with anti-neutrophil cytoplasmic antibody-associated vasculitis, or ANCA vasculitis. The ADVOCATE trial compared avacopan with the currently used standard of care regimen which consists of high doses of glucocorticoid (most commonly prednisone) which is administered to patients for months. The prednisone standard of care was the active comparator (prednisone active comparator standard of care, or SOC) against which avacopan was assessed in the a two-armed, randomized, controlled, and blinded trial. Subjects in both study arms received background therapy with rituximab or cyclophosphamide. The trial met both of its primary endpoints, showing that avacopan therapy without the need for daily prednisone could achieve disease remission at 26 weeks and sustained remission at 52 weeks, as assessed by the Birmingham Vasculitis Activity Score, or BVAS. BVAS remission at week 26 in the avacopan treated subjects was numerically superior and statistically non-inferior to the prednisone active comparator SOC control group, where BVAS remission was achieved in 72.3% of the avacopan treated subjects vs. 70.1% of subjects in the prednisone active comparator SOC control group ($p<0.0001$ for non-inferiority). Sustained remission at 52 weeks was observed in 65.7% of the avacopan treated subjects vs. 54.9% in the prednisone active comparator SOC control group, achieving both non-inferiority and superiority to prednisone active comparator SOC ($p=0.0066$ for superiority of avacopan). Reduction in overall burden of disease management and improvement in quality of life was also demonstrated through key secondary endpoints, including improved kidney function and reduction of adverse events and illnesses associated with steroids, such as prednisone.
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> We plan to file a New Drug Application, or NDA, with the U.S. Food and Drug Administration, or FDA, in mid-2020 and, if the NDA is approved, to commercialize avacopan in the United States on our own and internationally through our kidney health alliance with Vifor Fresenius Medical Care Renal

> Pharma Ltd. and its affiliates and sublicensees, or collectively, Vifor. We are also developing avacopan in other indications, including complement 3 glomerulopathy, or C3G, and hidradenitis suppurativa, or HS.
>
> ***Avacopan (CCX168)—Inhibition of Complement-Mediated Pathways in Orphan Diseases***
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> Avacopan (formerly CCX168) is our lead drug candidate. It is a potential first-in-class, orally-administered molecule that employs a novel, highly targeted mode of action in the treatment of ANCA vasculitis and other complement-driven autoimmune and inflammatory diseases. ANCA vasculitis is an orphan, severe, and often fatal autoimmune disease that is characterized by elevated levels of autoantibodies called anti-neutrophil cytoplasmic autoantibodies and by inflammation that can affect many different organ systems, and commonly involves the kidneys. ANCA vasculitis affects approximately 40,000 to 75,000 people in the United States, with between 4,000-9,000 new cases each year; similarly, ANCA vasculitis affects approximately 50,000 to 100,000 people in Europe, with between 5,000-10,000 new cases each year.
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> We have successfully completed and reported positive topline clinical data from our pivotal Phase III clinical trial of avacopan for the treatment of ANCA vasculitis, known as the ADVOCATE trial. ADVOCATE was a randomized, double-blind, active-controlled worldwide clinical trial which enrolled 331 patients with newly diagnosed or relapsing ANCA vasculitis at approximately 200 sites in the United States, Canada, Europe, Australia, New Zealand and Japan. The aim of the trial was to assess the safety and efficacy of avacopan in inducing and sustaining remission in patients with ANCA vasculitis.

34. On June 15, 2020, ChemoCentryx announced that its public offering of 5.2 million shares of its common stock had closed, and that the underwriters thereof exercised in full their option to purchase an additional 780,000 shares. All shares were sold by ChemoCentryx at the price of $58.00 each. Net proceeds to ChemoCentryx, after deducting underwriting discounts, commissions, and estimated offering costs, were $325.4 million.

35. On July 9, 2020, ChemoCentryx announced that it had submitted its New Drug Application to the FDA for avacopan in ANCA-associated vasculitis.[3] In this announcement, ChemoCentryx stated:

> The Company's NDA submission is supported by the results of its pivotal Phase III ADVOCATE trial, which demonstrated statistical superiority in sustaining remission at 52 weeks in the avacopan group compared to the prednisone group. In the trial, the avacopan group also showed significantly lower glucocorticoid toxicity, greater improvement in kidney function and greater improvement in health-related quality of life measures compared to the prednisone group. Finally, avacopan demonstrated favorable safety results in this serious and life-threatening

[3] https://ir.chemocentryx.com/news-releases/news-release-details/chemocentryx-submits-new-drug-application-us-fda-avacopan-anca.

> disease, with fewer subjects having serious adverse events in the avacopan group than in the prednisone group.

36. In addition, Defendant Schall stated:

> We have achieved a major landmark for ChemoCentryx with the submission of the NDA for avacopan in ANCA-associated vasculitis following our highly successful Phase III ADVOCATE trial . . . . There is an urgent need for a non-immunosuppressive, targeted therapy that can achieve and sustain remission in this organ- and life-threatening disease, while reducing the toxicities associated with daily steroid use. Submission of our NDA is a critical step toward addressing this unmet need, as we seek to improve patients' lives.

37. On August 10, 2020, ChemoCentryx issued a press release announcing its Second Quarter 2020 financial results. In the "Key Highlights" lauded in this release, the Company included that it had:

> Filed the New Drug Application (NDA) for avacopan in the treatment of ANCA-associated vasculitis in July. The Company's NDA submission is supported by the results of its pivotal Phase III ADVOCATE trial, which demonstrated statistical superiority in sustaining remission at 52 weeks in the avacopan group compared to the prednisone group. In the trial, the avacopan group also showed significantly lower glucocorticoid toxicity, greater improvement in kidney function and greater improvement in health-related quality of life measures compared to the prednisone group. Finally, avacopan demonstrated favorable safety results in this serious and life-threatening disease, with fewer subjects having serious adverse events in the avacopan group than in the prednisone group.

38. Also on August 10, 2020, ChemoCentryx held a call with analysts to discuss its financial results. On this call, Defendant Schall stated that "[f]rom ADVOCATE, there was good news here, too. A statistically significant improvement in clinically validated measurements of quality of life on avacopan therapy. And overall, avacopan also demonstrated a favorable safety result in this serious and life-threatening disease with fewer subjects having fewer numbers of serious adverse events in the avacopan group than in the steroid standard of care group."

39. Defendant Schall further stated on this same call:

> In the ANCA patient population, they're on background therapy for their disease. They're on also an amazing number, typically an amazing number of concomitant medications to control other complications of the therapy, prophylaxis for Pneumocystis jirovecii as a consequence of being under high doses of glucocorticoids and/or cyclophosphamide and rituximab. So that has its own problem, that conmed. They're trying to control their incipient diabetes and some of the bone problems with conmeds. They're really, really a challenged patient population. And one hopes going back to avacopan in ANCA vasculitis, by removing some of the need for these broadly immunosuppressive therapies, we also get rid of some of these nasty conmeds that give them so many AEs and SAEs.

> But even there in ANCA, we could show 40% fewer number of severe AEs in the avacopan group versus the prednisone standard of care group. So there is, seems to be, at many levels, very good safety advantages to using avacopan. But again, we'll let regulators and other sift through the data sets, and I won't say any more about that since it's under a filing right now. But it is pretty clear to us that HS population is, by and large, notwithstanding the fact that they have this really debilitating illness, and that causes them a lot of discomfort and pain in many areas of life physically and emotionally, they are, by and large, not under the burden of quite so many concomitant medications. And the safety database, although still blinded, the suggestion is that we have far fewer, across the board, safety events just in this patient population, full stop. And again, even in the blinded data set, nothing that seems out of the ordinary for this patient population.
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> So I think when the data come out, it will certainly add to and fundamentally enhance the picture of safety around avacopan, which we believe, based on evidence to date, both preclinical, off clinical, number of species and humans, both healthy and with ANCA vasculitis population, we believe will be a very supportive data package on safety as well. So we hope it will just further enhance that package. And if there are any outstanding questions that come out of ANCA vasculitis, which in a complex patient population, there always could be, but if there are any, we've got an equally large data set in hidradenitis suppurativa to check whether or not any of those kind of events are evident in HS. So I think it's going to be a real benefit to our overall packaging profile.

40. On September 17, 2020, ChemoCentryx announced that the FDA had accepted the avacopan NDA for the treatment of ANCA-associated vasculitis, setting a Prescription Drug User Fee Act ("PDUFA") goal data of July 7, 2021.[4] This release provided, in relevant part:

> The NDA included data from the global, Phase III ADVOCATE trial, which demonstrated statistical superiority in sustaining remission at 52 weeks in the avacopan group compared to the prednisone group. In the trial, the avacopan group also showed significantly lower glucocorticoid toxicity, greater improvement in kidney function and greater improvement in health-related quality of life measures compared to the prednisone group. Finally, avacopan demonstrated favorable safety results, with fewer patients having serious adverse events in the avacopan group than in the prednisone group.

41. On November 9, 2020, ChemoCentryx held an earnings call to discuss its Third Quarter 2020 financial results. On this call, Defendant Schall stated:

> Turning now to avacopan in the treatment of ANCA-associated vasculitis. As summarized in Slide 12, in Q3, we hit an historic milestone when the FDA notified us in September of their acceptance for review of our new drug application. The FDA set a PDUFA date goal of July 7, 2021. As for the question of an advisory committee, we intend to provide an update following the mid-cycle review meeting of the FDA, and we are preparing for one, nevertheless. The FDA's acceptance for review was followed by the announcement, just last week, of the European

[4] https://ir.chemocentryx.com/news-releases/news-release-details/chemocentryx-announces-fda-acceptance-avacopan-new-drug.

> Medicine Agency's acceptance for review, known as validation, of the marketing authorization application for avacopan in ANCA vasculitis, with a decision expected in the second half of 2021.
>
> As many of you know, the cornerstone of our submission to the regulatory agencies has been the data from the pivotal Phase III ADVOCATE clinical trial, which demonstrated statistical superiority of the avacopan group and sustaining remission at 52 weeks compared to the prednisone group. The results of the ADVOCATE study were presented last month in an oral abstract session during the American Society of Nephrology's Kidney Week 2020 Reimagined Meeting. They were presented by the renowned nephrologist, David Jayne, MD, Professor of Clinical Autoimmunity at the University of Cambridge in England. Dr. Jayne's presentation highlighted the potential of avacopan to offer new hope to patients who suffer from this incurable orphan disease. And just this last Friday, no less an expert than Professor Peter Merkel, MD, the Chief of Rheumatology at the University of Pennsylvania, gave a plenary session at -- on the ADVOCATE results at the American College of Rheumatology Convergence 2020 Meeting.
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> Professor Merkel delved into many important aspects of the avacopan data set, including highlighting some important features at both weeks 26 and weeks 52 in the trial result. As Dr. Merkel put it, and I'm alluding now to slide -- the next slide in the deck that you can see with the week 26 and 52 data. As Dr. Merkel put it, there are some intriguing findings to explore in the subgroups. Patients who had relapsing disease had even better benefit from avacopan at 26 and week 52. However, this should not imply that patients with newly diagnosed disease did not benefit from avacopan, because while remission rates with avacopan in newly diagnosed were about the same as the Prednisone group, remember, the patients receiving avacopan achieved this benefit without receiving daily glucocorticoids and their negative consequences. Similarly, said Professor Merkel, there were findings that patients who were MPO-positive received extra benefit and the patients who received rituximab as background therapy, seemed to receive extra benefit as well.

42. On this same call, an analyst asked Defendant Schall "Did the FDA indicate any review issues? And is there any update around the agency's view around an AdCom?" Defendant Schall responded:

> All of our interactions with the agency so far, again, without going into any real detail because we are under review. But to my mind, have been straightforward and expected. And I think we have ready access and have had ready access to all the answers so far for the queries. So I have not seen personally anything unusual or anything that, again, we did not fundamentally anticipate and for which we've been, quite frankly, ready. So I think it's going forward in a very reasonable, straightforward, logical way. And again, I won't say anything more than that because I'm sensitive to making sure we're not talking too much about a file under review.
>
> AdCom, we expect to know something more definite after the FDA's mid-cycle meeting. And I think probably the public calendars will tell you what that is. As soon as we know, we will let the community know. We have always, even before we filed the NDA, been presuming and preparing for an AdCom. Why is that? Number one, this is a new medical entity. It's not been reviewed or approved for

any other indication, already kind of putting you into the presumptive AdCom bucket, at least in my view, historically. Second, we're dealing with an orphan indication in ANCA vasculitis. And frankly, the agency has only truly reviewed an ANCA registration package but once before. And that was when rituximab, given in combination with the daily glucocorticoids was offered as an alternative to cyclophosphamide given in combination with daily glucocorticoids. And that was some time ago. So it's not as if it's a garden-variety indication where it's formulaic in terms of how to review an application. So again, oftentimes, that will trigger an AdCom.

43. On this same November 9, 2020 earnings call, Defendant Schall further stated:

Well, I hate to even presume to think about what the agency might think or say and certainly don't want to think -- to discuss any discussions with them until those are all done. But let me put it this way. Look, fundamentally, this is the longest randomized trial ever done in ANCA vasculitis, right? The randomized blinded trial, 52 weeks, continuous dosing and following. Look, that's not been done before. So we've got the biggest data set by 6 months. That's important because it informs a lot of discussions. So without thinking yet about what the agency may or may not say, they'll look at the data in their own way, obviously, but the data kind of speak for themselves. But I will tell you this, it sounds like we're already informing new discussions in the physician community, because the fact of the matter is, if you have, a, evidence that the hardest people to treat, the anti-MPO relapsers are pretty -- are notoriously difficult to treat. The MPA diagnosis, which goes along more or less with MPO-positivity, really difficult to get a handle on, especially with relapsers.

But fundamentally, I think the more subtle and for me, the more profound point is that, my goodness, when you look at the fact that avacopan not only had a really just a general improvement in relapse risk -- reducing relapse risk by some 54% and those were 2 charts shown in these meetings as Kaplan-Meier graphs where avacopan was clearly advantageous in the population. And part of that comes from that really interesting advantage that avacopan has with -- when given with rituximab as background therapy versus daily prednisone with rituximab as background therapy. 71% still in remission at week 52 versus 56% with the prednisone group. The important point here is we ran this trial according to rituximab's label at the time. And it was fully enrolled under the old rituximab label, which was you don't give rituximab except for that first course of therapy, that's 4 weekly infusions, spaced by a week. So they get up to 4 weeks. You don't top them up after that under the original label.

This data, some people have criticized us for that, like we had a choice to begin with, which we didn't. But in fact, the more enlightened discussions that I've heard, especially recently are no, the data actually show you don't need to keep immunosuppressing people with rituximab. That's a large end, 107 people per group were following. So they didn't get ritux -- they're totally matched except for prednisone versus avacopan. They didn't get any additional rituximab. So avacopan was kind of monotherapy, right? They didn't get any azathioprine or anything else after the ritux. And people are really, really markedly in remission at the end of 52 weeks. So that's an important discussion to have. So I don't know how that will play out. And again, I don't want to make too much or too little of that observation, but I think it's compelling, and I think it's starting to inform some new discussions.

44. On February 17, 2021, ChemoCentryx issued a press release announcing that the "Results of the Pivotal Phase III ADVOCATE Trial of Avacopan for the Treatment of ANCA-Associated Vasculitis" would be published in *The New England Journal of Medicine*.[5] This release provided, in relevant part:

> ANCA-associated vasculitis is a systemic auto-immune disease in which over-activation of the complement system further activates neutrophils, leading to inflammation and eventual destruction of small blood vessels. This results in organ damage and failure, with the kidney as the major target, and is fatal if not treated.
> "The results of the ADVOCATE trial are transformational and demonstrate the potential of avacopan to offer a substantial change in the treatment paradigm for ANCA-associated vasculitis," said Peter A. Merkel, M.D., MPH, Chief of Rheumatology and Professor of Medicine and Epidemiology at the University of Pennsylvania. "Current treatment for ANCA-associated vasculitis consists of combining months of daily glucocorticoids ("steroids" such as prednisone) with other immunosuppressive medications. Use of prednisone is associated with significant side-effects, including infections, diabetes mellitus, weight gain, and other problems. The ability of avacopan to replace prednisone and help patients achieve sustained remission is a significant and exciting advance for the treatment of patients with ANCA-associated vasculitis."
>
> "The ADVOCATE trial clearly demonstrates avacopan's ability to improve kidney function, measured by eGFR, in ANCA-associated vasculitis, and was recently reinforced in another orphan kidney disease, C3 Glomerulopathy. This is a significant advantage over other treatment options that often come with added toxicities and will likely lead to reduced risk of kidney failure over the longer term," said David Jayne, M.D., Director of the Vasculitis and Lupus Service, Addenbrooke's Hospital in Cambridge.
>
> The ADVOCATE trial was a global, randomized, double-blind, active-controlled, double-dummy Phase III trial in 331 patients with ANCA-associated vasculitis in 20 countries. Eligible patients were randomized to receive either avacopan or oral prednisone. In addition, all patients received standard background therapy of either: (a) rituximab for 4 weeks; or (b) cyclophosphamide for 13 weeks followed by azathioprine/mycophenolate, evenly balanced between the avacopan and prednisone groups.
>
> The study met both of its primary endpoints, demonstrating disease remission at 26 weeks and sustained remission at 52 weeks, as assessed by the Birmingham Vasculitis Activity Score (BVAS). Specifically, BVAS remission at week 26 was achieved in 72.3% of the avacopan treated patients vs. 70.1% of subjects in the prednisone group ($p<0.0001$ for non-inferiority). Sustained remission at 52 weeks was observed in 65.7% of the avacopan treated subjects vs. 54.9% in the prednisone group, achieving both non-inferiority and superiority to the prednisone group ($p=0.007$ for superiority of avacopan).

[5] https://ir.chemocentryx.com/news-releases/news-release-details/chemocentryx-announces-publication-new-england-journal-medicine.

Additionally, results published in the NEJM also show that, compared to the prednisone group, avacopan treatment:

- Reduced the risk of vasculitis relapse by 54%; there was a 10.1% relapse rate in the avacopan group compared to 21.0% in the prednisone group.
- Demonstrated greater improvement in kidney function, with a mean increase from baseline to week 52 in estimated glomerular filtration rate (eGFR) of 7.3 mL/min/1.73 m^2 with avacopan therapy vs. an increase in eGFR of 4.1 mL/min/1.73 m^2 in the prednisone group, and the difference between groups was 3.2 mL/min/1.73 m^2 (95% CI, 0.3 to 6.1).
- Significantly lowered glucocorticoid toxicity, with avacopan therapy 39.7 vs. 56.6 in the prednisone group in the Glucocorticoid Toxicity Index (GTI) Cumulative Worsening Score with a difference between groups of −16.8 points (95% CI, −25.6 to −8.0), and 11.2 with avacopan therapy vs. 23.4 for the prednisone group in the GTI Aggregate Improvement Score, with a difference between groups of −12.1 points (95% CI, −21.1 to −3.2).
- Led to greater improvement in health-related quality of life, measured by the Short Form 36 (SF-36) version 2 and the EuroQOL-5D-5L instrument (both Visual Analogue Scale and EQ Index), compared to the prednisone group.

Avacopan demonstrated favorable safety results in this serious and life-threatening disease, with fewer subjects having serious adverse events in the avacopan group than in the prednisone group.

The U.S. Food and Drug Administration (FDA) is evaluating avacopan for the treatment of ANCA-associated vasculitis and has set a Prescription Drug User Fee Act (PDUFA) target goal date of July 7, 2021.

45. On March 1, 2021, ChemoCentryx reported its Fourth Quarter and Full Year 2020 Financial Results. On the same day, the Company issued a press release announcing these results.[6] In this release, Defendant Schall stated:

> Inexorably our march of progress advances, drummed on by the call to improve the lives of patients enduring diseases with grossly inadequate treatments . . . . With regulatory applications for avacopan in ANCA-associated vasculitis accepted for review on three continents, we are preparing for our first commercial launch. In my view, avacopan has the potential to transform the lives of patients suffering from debilitating and intractable diseases, as demonstrated by the results not just in ANCA-associated vasculitis but also from our clinical trials in HS and C3G. We plan to launch a Phase III trial of avacopan in patients with severe HS in 2021, and to discuss the regulatory pathway for avacopan in C3G. Meanwhile, we are on track to initiate our next cycle of clinical development in 2021, with avacopan in lupus nephritis and – breaking entirely new ground - our orally-administered small molecule checkpoint inhibitor CCX559, designed to be a next generation cancer

[6] https://ir.chemocentryx.com/news-releases/news-release-details/chemocentryx-reports-fourth-quarter-and-full-year-2020-financial.

> treatment. We sense at ChemoCentryx the opportunity to transform the therapeutic landscape to the benefit of patients – and we intend to seize it.

46. On April 29, 2021, just five days before the release of the FDA's Briefing Document, described in greater detail *infra*, ChemoCentryx issued a press release reporting its First Quarter 2021 financial results and recent highlights.[7] In this release, Defendant Schall stated:

> Momentum builds with each passing quarter, bringing us closer to our goal of bringing novel, precisely targeted medicine to those that need it most . . . . At our R&D Day earlier this month, two world-renowned clinicians outlined the unmet needs in ANCA-associated vasculitis and the data driving their conviction that avacopan could become a landscape-changing therapy. We are well prepared and look forward to providing our views at the FDA Advisory Committee meeting on this topic in just a few days. During our R&D Day we also took the opportunity to establish how our novel small molecule PD-1/PD-L1 inhibitor CCX559 could transcend current limitations in the treatment of cancer. Meanwhile we are progressing toward our next cycle of clinical trials: a Phase III trial of avacopan in patients with severe HS; the initiation of clinical development of avacopan in lupus nephritis, and our first in human studies of the novel orally administered checkpoint inhibitor CCX559 in cancer patients. We look forward to an historic year of 2021 at ChemoCentryx, and we will devote all our energies to making the dream of breakthrough new therapies a reality for patients.

47. Also on April 29, 2021, ChemoCentryx held a call with analysts to discuss its First Quarter 2021 financial results. On this call, Defendant Schall stated:

> I think there's a lot of misconceptions about what is current "standard of care" there and there are some facts that have changed since we started the trial. But let me put it -- let me be very clear. We tried to make the ADVOCATE trial as close to real-world practice as possible. I -- that includes steroid regimen and tapering, both then best practice and, in fact, that's now best practice. We tried to make the background medication of either cyclophosphamide or rituximab as close to real-world practice. And in fact, we were completely aligning ourselves with the label of all those medications at the time, including rituximab.
>
> So what we got was an excellent trial design that reflected then real word practice. And still, to a large extent now, the one thing that has changed is rituximab label was expanded towards the very end of the ADVOCATE trial by the way to allow for increased frequency of dosing. So before it was essentially one regimen at the start of the treatment phase, which is 4 infusions spaced by 1 week. And now you can top up according to the label as frequently as every 6 months or so.
>
> Now while that is becoming an emerging paradigm, especially for patients that have a history of ANCA-associated vasculitis with relapse, the latest figures I saw, by the way, for newly diagnosed disease, I don't know if that's yet been adopted as the majority paradigm. So I think while rituximab's label has expanded fairly recently, I'm not sure I would call it exactly a changed standard of care. But it is a very fair point to say, "Well, look, rituximab is used ever more frequently." All the

[7] https://ir.chemocentryx.com/news-releases/news-release-details/chemocentryx-reports-first-quarter-2021-financial-results-and.

> better the features of the ADVOCATE trial actually allow us to leapfrog to what I think is the gold standard, which would be better for a maintenance therapy once people are quiescent. How would you do that trial? You do a double-blind, randomized placebo-controlled trial.
>
> And as I referred to in my remarks, de facto, you can get some of that information from weeks 26 to 52 in the ADVOCATE trial from the 65% of the people in that trial who had avacopan plus rituximab as a start and then went on to have no further medication as the trial were on. So they didn't get tapped up with rituximab. What did we see? We saw about a 71% sustained remission in the avacopan group versus a 50 -- middle 50% remission in the prednisone group. And this is the rituximab's staff alone. And it's not a tiny number of people. It's 200-plus people. So it's bigger than the whole RAVE trial.
>
> So what that tells us is that we have a very good way of maintaining remission after people get to a quiescent state at that first 26 weeks, and there isn't a need to give them necessarily more rituximab. And rituximab is not without its consequences. So it's at least an observation. Is it a trial designed to answer that question? No. But it is a feature of this trial that does shed light on that question. Could avacopan be used as a monotherapy in a maintenance surgery? And the answer is, well, these data suggest that it could., And that's what Dr. Merkel and Dr. Jayne alluded to in their remarks at both international congresses and Dr. Jayne at the R&D Day.
>
> So I think that's how best I would answer the question. We did an excellent trial. We reflect standard real-world practices at the time and still. And the fact that we didn't add additional rituximab actually gives a feature to our trial, which I think is very valuable. Finally, again, rituximab is a changing landscape. It's not used routinely, I think, even at this point, for newly diagnosed people in the second 6 months. It's mostly reserved for people with the history of relapse. So that's -- I think that's what I would put to the community at this point. It's again a set of observations based on data.

48. Importantly, in this April 29, 2021 call, Defendant Schall acknowledged that ChemoCentryx had "now received the FDA's briefing book for the Advisory Committee."

49. The statements in ¶¶ 22-33, 35-48 were materially false and misleading and omitted to disclose material information. Specifically, Defendants misrepresented and/or failed to disclose to investors that: (1) the study design of the Phase III ADVOCATE trial presented issues about the interpretability of the trial data to define a clinically meaningful benefit of avacopan and its role in the management of ANCA-associated vasculitis; (2) the data from the Phase III ADVOCATE trial raised serious safety concerns for avacopan; (3) these issues presented a substantial concern regarding the viability of ChemoCentryx's NDA for avacopan for the treatment of ANCA-associated vasculitis; and (4) as a result of the foregoing, Defendants' public statements were materially false and misleading at all relevant times.

50. Defendants knew, or in reckless disregard for the truth should have known, that at the time the statements in ¶¶ 22-33, 35-48 were made, they were false and/or misleading, and/or failed to disclose material information to investors.

The Truth Emerges

51. On May 4, 2021, in advance of the AdCom scheduled for May 6, 2021, the FDA released the Briefing Document concerning ChemoCentryx's NDA #214487 for avacopan. In this Briefing Document, the FDA noted that ChemoCentryx had "submitted the results of a single phase 3 study, CL010_168, and two phase 2 studies, CL002_168 and CL003_168. The focus of the AAC discussion will be data from Study CL010_168, also referred to as ADVOCATE, that compared avacopan to standard of care . . . in patients with AAV; patients in both arms received a background of either rituximab or cyclophosphamide standard induction regimen."[8] The FDA continued in the Briefing Document: "***[c]omplexities of the study design, as detailed in the briefing document, raise questions about the interpretability of the data to define a clinically meaningful benefit of avacopan and its role in the management of AAV***." (Emphasis added).

52. The FDA Briefing Document continued: "[a]lthough primary efficacy comparisons were statistically significant, ***the review team has identified several areas of concern, raising uncertainties about the interpretability of these data and the clinical meaningfulness of these results*** . . . ." (Emphasis added). These concerns included:

> (1) At Week 26, the proportion of patients in disease remission in the avacopan group (72.3%) was non-inferior to the prednisone group (70.1%) according to the Applicant's testing plan. However, superiority was not met. ***In pre-submission communications, FDA stated that a non-inferiority comparison would not be sufficient to show that avacopan can replace glucocorticoids as it would be difficult to establish whether avacopan is effective or whether rituximab/cyclophosphamide was the primary driver of the efficacy in both treatment arms. In addition, the Agency expressed concerns about the ability to adequately justify an acceptable non-inferiority margin, given that there were no historical trials appropriate to estimate the contribution of glucocorticoids to the treatment effect of glucocorticoids and cyclophosphamide or rituximab in the control arm.*** As discussed below, the justification for the non-inferiority (NI) margin was based on studies of different types of vasculitides, with different concomitant therapies, and of various designs that would not be considered appropriate to inform a NI margin for the study.

[8] "AAV" refers to ANCA-associated vasculitides.

(2) Interpretation of the non-inferiority at Week 26 is further limited by the large number of patients in the avacopan arm (86%) who received non-study supplied glucocorticoids from Week 0 to 26. While the mean cumulative glucocorticoid dose per patient over Week 0 to 26 was lower (1072.9 mg) in the avacopan-treated patients compared to the mean cumulative dose in the prednisone-treated patients (3192.5 mg), the non-inferiority assessment is not a comparison of avacopan vs. prednisone, but instead avacopan plus lower dose glucocorticoids vs. higher dose glucocorticoids. At this time, it is not clear how much reduction in glucocorticoids would be considered clinically meaningful and if the protocol-specified higher dose of glucocorticoids is required for control of disease activity. Therefore, the interpretability and meaningfulness of this comparison is challenging. This issue is further discussed below under Glucocorticoid Use.

(3) The clinical pharmacology program has identified avacopan as a CYP3A4 inhibitor that has the potential to increase exposures to systemic glucocorticoids which are CYP3A4 substrates, raising further uncertainties about the true difference in glucocorticoid exposures and its impact on the non-inferiority comparisons between the two groups at Week 26, and respectively the proposed role of avacopan as a steroid-sparing agent, as glucocorticoid exposures were not assessed in Study CL010_168.

(4) At Week 52, there was a disparity in observed treatment effects between the subgroups that received rituximab and cyclophosphamide (IV and oral) induction treatment. The estimated risk difference for disease remission at Week 52 was 15.0% (95% CI: [2.2%, 27.7%]) in the subgroup receiving induction with rituximab and 3.3% (95% CI: [-14.8%, 21.4%]) in the cyclophosphamide plus maintenance azathioprine subgroup (Table 10). ***Based on the data, there is no evidence of clinically meaningful treatment effect in the cyclophosphamide induction subgroup.*** Further, the treatment comparison in the complementary rituximab induction subgroup may not be considered meaningful because these patients did not receive maintenance therapy, i.e., due to undertreating of patients, the effect observed in the rituximab subgroup may not represent a clinically meaningful treatment effect compared to standard of care. Thus, the observed superiority at Week 52 may be a result of the treatment difference in the subgroup receiving induction with rituximab. We note that, at the time the study was designed, repeat dosing with rituximab was not established as maintenance therapy; however, long-term immunosuppression had been demonstrated to reduce disease relapse and was standard-of-care. The result of the subgroup analysis suggests the possibility that avacopan was efficacious only in the population who did not receive standard-of-care maintenance immunosuppression therapy and may be considered undertreated, raising questions about the adequacy of the comparisons and clinical meaningfulness of the avacopan effect at Week 52.

(5) ***There were differences between the assessments performed by the Investigator and the Adjudication Committee, most frequently related to the attribution of persistent vasculitis which was not captured in the modified BVAS administered in the study.*** Discrepancies between the Investigator and Adjudication Committee occurred in 17 patients at Week 52. Statistical analyses of the primary endpoint using the Investigator assessment of BVAS remission resulted in more conservative estimates of treatment effect, e.g., statistical significance for superiority would no longer be demonstrated with these scores. ***While the pre-specified analysis used the Adjudicator assessments, the assessment based on the Investigators, experienced in management of vasculitis, may better reflect real-world use.***

(Emphasis added).

53. In addition, the FDA raised serious concerns over the safety of avacopan. In the Briefing Document, the FDA noted:

> Deaths were rare, 2 in the avacopan arm and 4 in the control arm. Treatment-emergent infections, serious infections, and opportunistic infections were similar or fewer in the avacopan group. . . . One avacopan-treated patient had life-threatening hepatitis B reactivation during the follow-up period after rituximab treatment. A greater proportion of avacopan-treated patients had [adverse events] associated with hepatic abnormalities . . . including hepatobiliary disorders . . . . The proportion of patients with [adverse events] and [severe adverse events] within the hepatobiliary system organ class were also greater in the avacopan group . . . as compared to the prednisone group . . . . One patient had an [severe adverse event] of hepatocellular injury with increase in liver enzymes upon rechallenge with avacopan. One patient had an SAE of hepatic function abnormal with improvement in liver enzymes after discontinuation of avacopan; this patient was also found to have a positive hepatitis B DNA assay was treated with entecavir and did not resume avacopan. The Investigator assessed the event as possibly related to avacopan, but attribution of the event is confounded by the subsequent diagnosis of hepatitis B. One patient had an [severe adverse event] of severe hepatic function abnormal and met Hy's Law laboratory criteria with a liver biopsy that was suggestive of drug-induced hepatitis; however, this patient also received multiple other drugs associated with liver enzyme elevations. [Adverse events] associated with hepatic abnormalities led to drug discontinuation in 7 patients in the avacopan arm and 2 patients in the prednisone arm. In addition, there were 2 patients with angioedema (1 serious) in the avacopan group, compared to none in the prednisone group. ***Given the small safety database, conclusions are limited, however, imbalances in hepatotoxicity, liver enzyme elevations, and angioedema are observed despite the small sample size.***

(Emphasis added).

54. In the "Benefit-Risk Considerations" section of the Briefing Document, the FDA noted that "AAV is a rare and serious disease associated with high morbidity and mortality. It is also a disease with high unmet need for new therapies. Given these considerations, in principle, a single adequate and well-controlled (AWC) study may be considered to establish substantial evidence of efficacy." The FDA continued, "***[h]owever, in CL010_168, there are substantial uncertainties around the Phas3 study design and results, raising questions about the adequacy of this single trial to inform the benefit-risk assessment.***" (Emphasis added). Among other concerns it raised in this section, the FDA wrote that "the Applicant has not provided adequate data or information that would isolate the effect of prednisone to inform the margin of the non-inferiority comparison in this study," "the interpretation of the non-inferiority assessment is

challenging," and "data from the clinical pharmacology program has identified avacopan as a CYP3A4 inhibitor that has the potential to increase exposures to systemic glucocorticoids which are CYP3A4 substrates, raising further questions about the true difference in glucocorticoid exposures and its impact on the non-inferiority comparisons between the two groups, and respectively the proposed role of avacopan as a steroid-sparing agent." The FDA further noted that although "statistical significance was observed for both non-inferiority and superiority at Week 52 for the primary endpoint, it is not clear if the comparisons between and prednisone arm beyond Week 26 are meaningful. Superiority of the avacopan arm over the prednisone arm was not achieved for remission at Week 26."

55. Analysts were stunned by the news and concerns raised by the FDA in the Briefing Document. For example, Piper Sandler commented that the Briefing Document raised "serious questions" about the Phase 3 ADVOCATE trial design and the analysis of avacopan's effect in treating ANCA-associated vasculitis. Similarly, JPMorgan called the Briefing Document "worse than expected," adding that the "negative tone/stance of the FDA documents is without a doubt concerning."[9]

56. On this news, the price of ChemoCentryx common stock plummeted over 45% in one day, down from its May 3, 2021 closing price of $48.82 to a May 4, 2021 close of $26.63 per share, on unusually high trading volume. Shares traded intraday as low as $17.79 each. This represents a one-day loss of approximately $1.5 billion in market capitalization.

57. The statements in ¶¶ 22-33, 35-48 were materially false and misleading and omitted to disclose material information. Specifically, Defendants misrepresented and/or failed to disclose to investors that: (1) the study design of the Phase III ADVOCATE trial presented issues about the interpretability of the trial data to define a clinically meaningful benefit of avacopan and its role in the management of ANCA-associated vasculitis; (2) the data from the Phase III ADVOCATE trial raised serious safety concerns for avacopan; (3) these issues presented a substantial concern regarding the viability of ChemoCentryx's NDA for avacopan for the treatment of ANCA-

[9] https://thefly.com/landingPageNews.php?id=3295987&headline=CCIX-ChemoCentryx-plunges-as-FDA-staff-raise-questions-about-avacopan-data1620152978 (last visited May 5, 2021).

associated vasculitis; and (4) as a result of the foregoing, Defendants' public statements were materially false and misleading at all relevant times.

58. Defendants knew, or in reckless disregard for the truth should have known, that at the time the statements in ¶¶ 22-33, 35-48 were made, they were false and/or misleading, and/or failed to disclose material information to investors.

59. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of ChemoCentryx's common stock, Plaintiff and other members of the Class have suffered significant losses and damages.

Class Action Allegations

60. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of a class of all persons and entities who purchased or otherwise acquired ChemoCentryx common stock between November 26, 2019 and May 3, 2021, inclusive, seeking to recover damages caused by Defendants' violations of the federal securities laws and to pursue remedies under §§ 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5. Excluded from the Class are Defendants, directors and officers of the Company, as well as their families and affiliates.

61. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court.

62. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class which predominate over questions which may affect individual Class members include:

a. Whether the Exchange Act was violated by Defendants;

b. Whether Defendants omitted and/or misrepresented material facts;

c. Whether Defendants' statements omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;

d. Whether Defendants knew or recklessly disregarded that their statements were false and misleading;

e. Whether the price of the Company's stock was artificially inflated; and

f. The extent of damage sustained by Class members and the appropriate measure of damages.

63. Plaintiff's claims are typical of those of the Class because Plaintiff and the Class sustained damages from Defendants' wrongful conduct alleged herein.

64. Plaintiff will adequately protect the interests of the Class and have retained counsel who are experienced in class action securities litigation. Plaintiff has no interests that conflict with those of the Class.

65. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

Fraud on the Market

66. Plaintiff will rely upon the presumption of reliance established by the fraud-on- the-market doctrine that, among other things:

a. Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

b. The omissions and misrepresentations were material;

c. The Company's common stock traded in efficient markets;

d. The misrepresentations alleged herein would tend to induce a reasonable investor to misjudge the value of the Company's common stock; and

e. Plaintiff and other members of the class purchased the Company's common stock between the time Defendants misrepresented or failed to disclose material facts.

67. At all relevant times, the markets for the Company's stock were efficient for the following reasons, among others: (i) the Company filed periodic public reports with the SEC; and (ii) the Company regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the major news wire services and through other wide-ranging public disclosures such as

communications with the financial press, securities analysts, and other similar reporting services. Plaintiff and the Class relied on the price of the Company's common stock, which reflected all information in the market, including the misstatements by Defendants.

No Safe Harbor

68. The statutory safe harbor provided for forward-looking statements under certain conditions does not apply to any of the allegedly false statements pleaded in this Complaint. The specific statements pleaded herein were not identified as forward-looking statements when made.

69. To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.

Scienter Allegations

70. As alleged herein, Defendants acted with scienter since Defendants knew that the public documents and statements issued or disseminated in the name of the Company were materially false and/or misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, the Individual Defendant, by virtue of his receipt of information reflecting the true facts regarding ChemoCentryx, his control over, and/or receipt and/or modification of ChemoCentryx's allegedly materially misleading misstatements and/or his associations with the Company which made him privy to confidential proprietary information concerning ChemoCentryx, participated in the fraudulent scheme alleged herein.

Loss Causation

71. As alleged in greater detail herein, on May 4, 2021, the FDA released the Briefing Document raising serious concerns about, *inter alia*, the study design of the Phase III ADVOCATE trial and the safety profile of avacopan for the treatment of ANCA-associated vasculitis.

72. On this news, the price of ChemoCentryx common stock plummeted over 45% in one day, down from its May 3, 2021 closing price of $48.82 to a May 4, 2021 close of $26.63 per

share, on unusually high trading volume. Shares traded intraday as low as $17.79 each. This represents a one-day loss of approximately $1.5 billion in market capitalization.

CAUSES OF ACTION

Count One

Violations of § 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder

73. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

74. During the Class Period, Defendants disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose the material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading.

75. Defendants violated § 10(b) of the Exchange Act and Rule 10b-5 in that they: (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon those who purchased or otherwise acquired the Company's securities during the class period.

76. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for the Company's common stock. Plaintiff and the Class would not have purchased the Company's common stock at the price paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by Defendants' misleading statements.

Count Two

Violations of § 20(a) of the Exchange Act

(Against the Individual Defendant)

77. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

78. The Individual Defendant acted as a controlling person of the Company within the meaning of § 20(a) of the Exchange Act as alleged herein. By virtue of his high-level positions at

the Company, the Individual Defendant had the power and authority to cause or prevent the Company from engaging in the wrongful conduct complained of herein. The Individual Defendant was provided with or had unlimited access to the documents described above which contained statements alleged by Plaintiff to be false or misleading both prior to and immediately after their publication, and had the ability to prevent the issuance of those materials or to cause them to be corrected so as not to be misleading.

Prayer for Relief

Plaintiff prays for relief and judgment as follows:

a) determining that this action is a proper class action pursuant to Rule 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure on behalf of the Class as defined herein, and a certification of Plaintiff as class representative pursuant to Rule 23 of the Federal Rules of Civil Procedure and appointment of Plaintiff's counsel as Lead Counsel;

b) awarding compensatory and punitive damages in favor of Plaintiff and the other class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including pre-judgment and post- judgment interest thereon.

c) awarding Plaintiff and other members of the Class their costs and expenses in this litigation, including reasonable attorneys' fees and experts' fees and other costs and disbursements; and

d) awarding Plaintiff and the other Class members such other relief as this Court may deem just and proper.

Jury Demand

Plaintiff demands a trial by jury in this action of all issues so triable.

May 5, 2021

Respectfully submitted,

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